Table 4.3.1.1: *Summary of studies reporting on the association between exposure to ETS and heart disease in adults. (cont.)*

First Author (Year)	Study Period	Study Population	Entry Criteria	Study Size
Case Control Studies				
Vechhia (1993)	1988-1989	Italy	M&F, 29-74 yrs, within GISSI-2 study; currently married neversmokers. Cases: first episode AMI Controls: hospital-based, disease not related to CVD	113 cases 225 controls
Cohort Studies				
Butler (1988)	1976-1982	Californian Seventh-Day Adventists USA	Spouse-pairs: married couples; AHSMOG: in concurrent air pollution study	11060 spouse-pairs, 6467 AHSMOG subjects; 20 unexposed cases
arland (1985)	1963, for 10 years	Californian retirement community, San Diego USA	F, married, aged 50-79 years	695 entered, 2 unexposed cases
irayama (1984)	1966-1981	29 Health Centre Districts in Japan	F, married, 40+years	91540 entered, 118 unexposed cases
ile (1989)	screened 1972-1976; 11.5 years on average	2 towns in West Scotland, area with high lung cancer incidence	M&F, 45-64 years	671M, 1784F entered, 30 unexposed cases

Table 4.3.1.1: *Summary of studies reporting on the association between exposure to ETS and heart disease in adults. (cont.)*

First Author (Year)	Study Period	Study Population	Entry Criteria	Study Size
Case Control Studies				
Humble (1990)	1960, for 20 years	Georgia USA	F, married, 40-74 years, disease free	513 entered, approx. 27 unexposed cases
Sandler (1990)	1963, for 12 years	Maryland USA	M or F; 25+ years	4162M, 14873F entered, 437F&248M unexp. cases
Svendsen (1987)	1973, for 7 years on average	18 cities in USA	M, married, 35-57yrs,high h.d. risk	1245 entered, 8 unexposed cases

All subjects in all studies were nonsmokers or neversmokers.

IHD: ischemic heart disease; CHD: coronary heart disease. AHD: atherosclerotic heart disease; MI myocardial infarction;

h.d.: heart disease.

Coherence

As discussed above, generally there is no conflict with generally known facts about the natural history and biology of the disease.

Experimental Evidence

The experimental studies of this association have been discussed above. Overall, this 'evidence' must be treated with considerable caution. Note also that it is not sufficient merely to observe that both incidence of heart disease and incidence of active smoking are decreasing, since there may be many other factors involved in this 'association'. For example, the reduced incidence of heart disease may be due to better management combined with improved diagnosis of cause of death.

Analogy

There are some difficulties in passing this test.

Any analogy with active smoking requires, among other things, assumptions of equivalence between exposure level, and between mainstream smoke and ETS constituents.

Some of the reported relative risks for ETS approach those reported for active smoking; this is difficult to defend since active smokers are also exposed to ETS.

As discussed earlier, any one of a large number of risk factors could have the same effect.

Overall, the above discussion leads to perhaps 3 out of the 9 tests being passed biological plausibility, coherence, experimental evidence), perhaps 2 about which there is insufficient evidence (experimental evidence and biological gradient), 1 for which there is a theoretical basis but which is not accounted for in the studies (temporality), and 3 which we believe are failed (strength, consistency, specificity).

Conclusion

While there is some evidence that ETS aggravates exercise induced ischaemia in persons with existing heart disease, it is our overall view that, based on the current data, a causal relationship between exposure to ETS and heart disease in adults in the general population cannot be asserted.

Table 4.3.1.1: Summary of studies reporting on the association between exposure to ETS and heart disease in adults.

First Author (Year)	*Study Period*	*Study Population*	*Entry Criteria*	*Study Size*
Case Control Studies				
Dobson (1991)	1988-1989	NSW Australia	Lower Hunter Region residents; Controls were in risk factor survey	M: 183 cases, 293 controls; F: 226 cases, 332 controls
Lee (1986)	1979-1982	10 hospital regions in England	M&F, 35-74 years, hospital inpatients; Controls: without one of 4 index diagnoses	M: 30 cases, 97 controls; F: 36 cases, 157 controls
He (1989)	1985-1987	Xijing, China	F; Controls: 34 population-based, 34 hospital-based	34 cases, 68 controls
He (1994)	1989-1992	Xi'an, China	F neversmokers with full time jobs, excl. if retired for 5 or more years	59 cases, 126 controls
Martin (1986)		Utah	Parents of high school students; never smoking women 30-39 years with data on spouse smoking	9172 spouse pairs, 7115 never smoking women, 23 cases
Palmer (1988)		USA	F, 20-64 yrs, in hospital-based study of post-oral contraceptive use&MI	336 married cases, 799 married controls

Platelets and Endothelium

Glantz and Parmley refer to several papers reporting that ETS increases platelet aggregation and damages endothelium, two events which may increase the risk of CHD. Several papers by Davis et al. (1985a, 1985b, 1986, 1987, 1989) are quoted. There are a number of weaknesses in these studies, not the least of which is a lack of correlation between platelet factor 4 and nicotine levels across individuals. There is also considerable variability between individuals. In Davis et al. (1985b) the before smoking values for platelet factor 4 ranged from 6.8 to 39.2 ng/ml (mean of 13.8) whereas after smoking values ranged from 7.0 to >100(mean 18.6). The significance of this variability is not explained.

Even accepting that platelet aggregation is increased it is a very big step to then propose that this is the mechanism by which ETS *causes* heart disease. Conceivably there may be a propensity for increased thrombus formation but only in those persons with a preexisting CHD condition and where there is clear endothelial denudation *and* subendothelial tissue damage -- that is where lesions are at an advanced stage. The other proposed mechanism by which platelets may play a role in the development of lesions is through the release of growth factors. While this was originally proposed by Ross and Glomset in 1973 as part of their response to injury hypothesis, this idea has been significantly modified (Ross, 1993). Whereas platelets may play a role in the late stages of the disease, other factors such as endothelial and monocyte derived growth factors and bFGF, as well as oxidised LDL (which can promote endothelial injury), are more likely to be involved in the early development. The effect of passive smoking on these factors is not known.

It is important to emphasise that probably none of the factors works alone in atherogenesis (Ross, 1993) but rather through a network of interactions including checks and balances. Confounding factors may be particularly important in this regard.

More recently there have been a number of publications investigating the effect of cigarette smoke on endothelium. Of particular interest is a paper by Lehr et al. (1993) showing that cigarette smoke elicits leucocyte adhesion to endothelium in hamsters and that this response is attenuated by superoxide dismutase (SOD). The model, however, is one of very heavy exposure to cigarette smoke and the results cannot be extrapolated to ETS. The significant attenuation by SOD, however, is important as it supports a role for antioxidants. Should ETS elicit leucocyte adhesion (very doubtful considering the magnitude and variability of the results

under conditions of heavy exposure) then dietary antioxidants could conceivably negate any deleterious effects. This highlights the importance of confounding factors, notably diet, referred to earlier.

The endothelial damage reported in the papers by Davis and colleagues also needs to be questioned. The endothelial cell counts are very low (about 2-4). Circulating endothelial cells, or ghosts, were counted in Neubauer chambers which are particularly inaccurate with low cell counts. From the personal experience of one of us (MJM) counts below 30 are suspect and ideally counts need to be 100 achieve a precision of around 5%. Thus counts reported as doubling from 2.3 to 4.8 (Davis et al., 1985a) are not reassuring. It must be emphasised that these changes occurred with *active* smoking. Extrapolation to ETS is not possible. The argument is advanced that endothelial loss is the key factor but in animal models the loss needs to be substantial *and* contiguous for intimal thickening to occur (Williams, 1991).

A further argument advanced by Glantz and Parmley is that ETS decreases the sensitivity of platelets to antiaggregatory prostacyclin PGI_2, thus increasing susceptibility to aggregation and thrombus formation. Generally the data appear to be sound but some points are not clear. For example in the paper by Burghuber et al. (1986) why are the sensitivity indices for smokers and nonsmokers before exposure to either active or passive smoking (Fig. 3 in Glantz & Parmley) so apparently different? Nonsmokers exposed to ETS (Fig. 3 right) appear to be little different from nonsmokers not exposed (Fig. 3 left). Presumably this is because the values for individuals vary considerably. If this is so then it is difficult to interpret the biological significance of any changes, especially with respect to ETS and atherogenesis. (At best, one would have to argue that what is important for an individual is a change in level, but not the level itself.)

Carcinogenic effects - the role of polycyclic aromatic hydrocarbons (PAHs)

Glantz and Parmley argue that atherosclerotic plaques arise due to the mutagenic actions of PAHs in ETS and cite a number of papers (Benditt & Benditt, 1977; Alber et al., 1977; Revis et al., 1984; Penn et al., 1981, 1986; Majesky et al., 1983; Randerath et al., 1988). At best the results are equivocal and the relationship to passive smoking very tenuous.

Several points need to be made. First the plaques analysed after injection of PAHs are not atherosclerotic lesions. They are myointimal thickenings. Second, apart

Study Quality

It is our opinion, based on the discussion in the previous section, that problems in study quality, which may lead to bias and misclassification, have not been adequately addressed and may still explain much, if not all, of an observed association.

Confounders

As detailed in the previous section, there is inadequate control of confounders.

There are over 200 identified risk factors for heart disease. While many of these are linked, no study controls for more than 6. Some of these, such as diet or previous heart disease, may completely explain any observed association.

Representativeness

Because of special study groups, differences between cases and controls, and poor control of confounders, considerable caution should be used in extrapolating the epidemiological results to other populations.

Consistency

In our opinion the relative risk estimates are not consistent across epidemiological studies. For example, excess risk estimates vary from 0.2 to 2.0, a ten-fold range, and in two instances they are actually negative.

Specificity

Exposure to ETS is not the only possible cause of heart disease. Moreover, specificity of magnitude is not established: many other risk factors have larger relative risks for heart disease than ETS exposure.

Temporality

As discussed in Section 2, the outcome depends on when the exposure is measured. Hence measures of current exposure are invalid without assumptions of constancy of exposure and confounders over time. Past exposure, however, requires recall with associated possible bias.

Wexler (1989, p.150) asserts that each of the studies to 1989 appears to provide adequate temporal association between ETS exposure and onset of cardiovascular disease.

Biological Gradient

As detailed above, dose response relationships are not consistent across the epidemiological studies which give relevant data. Any overall assessment is further conditional on possible unreported nonsignificant relationships in the other studies. Often, however, the numbers are simply too small or the measures too crude to allow an assessment of biological gradient.

Plausibility

The generally accepted view of atherogenesis is that it is a multifactorial problem with the potential for a large number of factors to initiate and aggravate the disease process, perhaps through just a few common pathways. Thus the effects of different risk factors on the pathology cannot necessarily be distinguished from each other. One proposed pathway is through endothelial injury and damage whereby following endothelial removal, or dysfunction of endothelial cells *in situ*, the balance between various cytokines and growth factors is altered to favour migration, growth and matrix synthesis of the vascular smooth muscle cells. In advanced stages, necrosis, which is often associated with lipid deposition, leads to lesion formation and may result in plaque rupture, thrombus formation and a subsequent myocardial or cerebral infarction.

It is biologically plausible that ETS could contribute to these processes and the papers reviewed earlier in this report comment on the numerous mechanisms. The weakness of the data supporting the claims for a causal relationship, however, has been commented on. Further it is not possible to estimate a relative contribution, if any, to the multifactorial biological process of lesion initiation and development other than be guided by the relative risk obtained through the epidemiological studies. As previously stated this relative risk is very small and has not yet been shown to be free of confounders. It must be emphasised that there are a very large number of plausible risk factors for atherosclerosis yet despite decades of research there is still no treatment which inhibits lesion development.

Table 4.3.1.2: *Summary of relative risk estimates of heart disease associated with exposure to ETS in adults. (cont.)*

Author (Year)	Subgroup	Crude RR (95% CI)	Adj. RR (95% CI)	Factors for which adjustment was made	Exposure-Response Results
Cohort Studies					
Butler (1988)	Females		1.4 (0.5-3.8)		Exsmoker:RR=1.0 (0.6-1.7) Current: RR=1.4 (0.5-3.8)
Garland (1985) Table 2	Females	3.5 (0.8-15)	2.9, p<0.1	age (also considered years of marriage, blood pressure, cholesterol, obesity)	Reported age-adjusted positive dose response
Hirayama (1984) Table 5	Females	1.0 (0.8-1.2)	1.2 (0.9-1.4)	age of wife	Reported sig., low to high: 1.1 (low), 1.3 (high) (no CI)
Hole (1989)	Males Females Total	1.6 (0.9-2.8) 3.8 (1.2-12) 1.1 (0.7-1.7)	2.0 (1.2-3.4)	age, sex (also considered class, BP, CHD, cholesterol, BMIs)	1-14cigs/day:RR=2.1 15+cigs/day:RR=4.1 Crude:3.0(0.9-11),4.8(0.7-1.3)
Humble (1990)	Females	insufficient data	1.6 (1.0-2.6)	age (also considered class, BP, cholesterol, BMI)	Reported dose response in some strata

Table 4.3.1.2: *Summary of relative risk estimates of heart disease associated with exposure to ETS in adults. (cont.)*

Author (Year)	Subgroup	Crude RR (95% CI)	Adj. RR (95% CI)	Factors for which adjustment was made	Exposure-Response Results
Cohort Studies					
Sandler (1990) (Helsing, Table 4)	Males Females	1.2 (0.9-1.5) 0.7 (0.6-0.8)	1.3 (1.1-1.6) 1.2 (1.1-1.4)	age, housing quality, marital status, years of schooling	*Males:* Score 1-5:RR=1.4(1.1-1.8); Score 6:RR=1.3(1.0-1.6) *Females:* Score 1-5:RR=1.4(1.1-1.8); Score 6:RR=1.3(1.0-1.6)
Svendsen (1987) Table 8 (Males)	*Spouse Smoking:* Death Heart attack/ Death *Work Exposure:* Death Heart attack/Death *Interaction**:* W+,C+ W+,C- W-,C+	 2.1 (0.7-6.5) 1.5 (0.9-2.5) insufficient data insufficient data	 2.2 (0.7-6.9) 1.6 (1.0-2.7) 2.6 (0.5-13) 1.4 (0.8-2.5) 1.7 (0,8-3.6) 1.2 (0.4-3.7) 1.0 (0.5-1.9)	age, blood pressure, cholesterol, weight, education, drinks/week age, wife's smoking status no adjustments stated	*Death:* Reported sig. trend, p=0.04: 1-19cigs/day:RR=0.9 (.1-7) 20+ cigs/day:RR=3.1(.9-11) *Death/Disease:* Reported negligible trend: 1-19cigs/day:RR=1.2 20+cigs/day: RR=1.8

*Calculated using the logit method from available data; **W+: spouse smoker, C+: coworker smoker

***Reported as 14.9 (estimated 95% CI 0.2-500) but argued by Mantel (see Lee, 1992, p.187) to be wrong: log(14.9) is the appropriate value

Table 4.3.1.2: *Summary of relative risk estimates of heart disease associated with exposure to ETS in adults.*

Author (Year)	Subgroup	Crude RR (95% CI)	Adj. RR (95% CI)	Factors for which adjustment was made	Exposure-Response Results
Case Control Studies					
obson 1991) ables 3,4	*Home Exposure:*			age, sex, prior history of heart disease	
	Males	1.0 (0.6-1.8)	1.0 (0.5-1.9)		
	Females	1.6 (1.1-2.4)	2.5 (1.5-4.1)		
	Work Exposure:				
	Males	0.9 (0.5-1.6)	1.0 (0.5-1.8)		
	Females	0.7 (0.2-2.1)	0.7 (0.2-2.6)		
e 986) ble 5	*Spouse Smoking:*			matched for sex, age, hospital region, ward, time of interview. RR's standardised for age, spouse smoking, if ongoing or ended marriage	*(Combined index)* *Males:* Score 2-4: RR=0.4 (0.2-1.0) Score 5-12: RR=0.4 (0.1-1.9) *Females:* Score 2-4: RR=0.5 (0.2-1.1) Score 5-12: RR=0.6 (0.2-2.0) (Adj. RR=0.6, 0.8 respectively)
	Males	1.3 (0.6-2.8)	1.2		
	Females	1.0 (0.6-1.7)	0.9		
	Total	1.0 (0.7-1.5)	1.0 (0.7-1.6)		
	Combined Index:				
	Males	0.4 (0.2-0.8)	results given by dose		
	Females	0.5 (0.3-1.0)			
	Combined	0.5 (0.3-0.8)			

Table 4.3.1.2: *Summary of relative risk estimates of heart disease associated with exposure to ETS in adults. (cont.)*

Author (Year)	Subgroup	Crude RR (95% CI)	Adj. RR (95% CI)	Factors for which adjustment was made	Exposure-Response Results
Case Control Studies					
He (1989)	Females	3.0 (1.3-7.2)	1.5 (1.3-1.8)	matched for age, race, residence, occupation; adj. for history of CHD, exercise, drinking history, hypercholesterolaemia	1-20cigs/day:RR=2.3 (.8-6.3) 21+cigs/day; RR=6.9 (2.2-22)
He (1994)	Females			adj. for age, hypertension history, type A personality, total cholesterol, high density lipoprotein cholesterol concentration	Reported sig. trends for exposure at work, using 4 exposure measures; additive effect of spouse and work exposure.
	Spouse	2.1 (1.1-4.3)	1.2 (0.6-2.7)		
	Work	2.5 (1.2-4.9)	1.9 (0.9-4.0)		
	Any	2.9 (1.3-6.)	2.4 (1.0-5.6)		
Martin (1986)	Females		2.6 (1.2-5.7)		Ex: RR=1.9 Current: RR=4.4 (Adj.=3.4)
Palmer (1988)	Females		1.2		'observed trend'
Vecchia (1993)	Males	1.0		sex, age, education, coffee, BMI, cholesterol, diabetes, hypertension, family history of MI	Ex: RR=0.9 (0.4-2.3) <15cigs/day: 1.1 (0.5-2.8) 15+cigs/day; 1.3 (0.5-3.4)
	Females	1.3			
	M&F combined		1.2 (0.6-2.5)		

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from Revis et al. (1984), new lesions were *not* induced; previously existing thickenings were increased in size. While Revis et al. did find evidence of increased numbers of plaques they occurred only with BaP, and not with BeP, DMBA or 2,4,6 trichlorophenol, and only in aorta. A dose response was not observed. Although tissues were examined for lipid droplets there are no photographs of the "lesions" thus it is difficult to assess the type of plaque. It is also difficult to be certain that the increased number of plaques was due to new plaques. It could be a function of recording method; that is very small existing plaques may have been below the detection threshold. It is not clear from the methods whether the counts were made by eye or with the aid of a microscope.

Penn et al. (1986) claim to provide support for the idea that plaques are monoclonal in origin since DNA collected from human coronary plaques can give rise to transformed cells in culture which can subsequently produce tumours in mice. This work, however, has been challenged by the results of other studies. Few et al. (1989) were not able to identify transforming sequences in DNA from carotid plaques and DNA damaged during isolation from normal cells can transform cells in culture (Bishop, 1987).

The paper by Randerath et al. (1988) reports on the effects of topical application of cigarette smoke condensate to skin of mice. Their claim, however, that the resulting DNA damage in heart and lung tissue, following cutaneous penetration, implies a route for passive smoke is stretching the conclusions to the absolute limit. Leaving aside the question as to whether or not the DNA damage would result in carcinogenesis in the lung or heart (the latter a very rare event) what is not addressed is the question of concentration differences between dermal exposure to passive smoke versus topical application of a condensate.

Direct Effect of ETS on Plaque Growth

Penn and Snyder (1993) reported that inhalation of sidestream smoke accelerates the development of arteriosclerotic plaques in young cockerels exposed for 6 hours per day, 5 days a week over 16 weeks. Notwithstanding concerns over the exposure levels (Coggins, 1993), the method of measuring plaque growth is questionable. Penn and Snyder use a plaque index which uses lumenal circumference to standardise plaque areas. This method, however, is very susceptible to bias since even a small difference can produce erroneous results. For example if the vessels of the exposed group were slightly smaller (the weights of the cockerels at the end of the experiment are not given) then the net effect

would be an increase in the plaque index without any change in plaque area. Since Penn and Snyder do not reproduce any of the raw data in their paper, nor any measure of variance such as standard deviation, it is not possible to conclude, as they do, that there is an increase in plaque size.

Conclusion

Taken together the biological data do not support a causal relationship between ETS and heart disease. At best there is a possibility of aggravation of existing heart disease. While acute effects, such as endothelial loss and platelet aggregation, can be demonstrated the impact of these on the disease process can only be conjectural. A further difficulty, and one not generally addressed in the biological studies, is the interaction of ETS with other risk factors for CHD. Since atherosclerosis is believed to be a multifactorial process, interactions and confounders preclude any firm statements about the biological effects of ETS on the initiation and development of lesions.

4.3.4 Does Exposure to ETS Cause Heart Disease in Adults?

We now assess the scientific evidence for a causal relationship between ETS and heart disease in adults.

Strength

It is our opinion that neither the epidemiological nor the biological data indicate a strong association.

Overall, the relative risks are below 2. Because of the small size and large variability in the epidemiological studies, other factors may account for any individual and overall excess risk.

Chance

Chance has not been ruled out as a possible explanation of the observed increase in relative risk in the 14 individual studies: less than half report relative risk estimates which are statistically significantly greater than unity. Over all the studies, a positive association is more compelling but still not strong.

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